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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,588	11/29/2001	Chen Xing Su	10209.353	6233

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06/18/2002

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EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/18/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/997,588

Applicant(s)
Su et al.

Examiner
Patricia Patten

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 23, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 13-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-23 are pending in the application.

Applicant's election without traverse of Group I, claims 1-12 in Paper No. 3 is acknowledged. Claims 13-23 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claims 1-12 have been presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites 'the step for providing.' This phrase lacks antecedent basis in the claim in that the word 'step' was not previously mentioned. It is suggested that the claim be amended to read: 'A method for reducing cellular damage comprising providing a dietary supplement which is consumed, to reduce cellular damage...'. The terms 'for providing' and 'for consumption' are not clearly delineated because it is not understood if these are actually limitations or not; 'for consumption' is considered to be analogous to 'such as' in that 'such as' is not a clear indication that the limitation is actually occurring in the claim: Regarding claim, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Rewording the claim as provided supra will overcome this rejection.

Claims 2 and 10 are confusing in that they recite 'further comprising the step for providing a recommended use of the dietary supplement...'. The claims lack antecedent basis in that claims 1 and 9 do not recite a 'packaging' or 'manufacturing' means which could include a 'recommended use.' The Examiner is not sure whether Applicants intend for these claims to mean that the packaging contains this 'recommended use' or if the method is being limited to the particular dosage requirement. The recitation of a dosage on a packaging is merely an intended use of a product, and does not materially change the method steps of the claim. If Applicants intend for claim 2 to further limit the actual method for reducing cellular repair (via

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dosage), it is suggested that the claim be changed to; '....A method as recited in claim 1, wherein said providing includes one of:....' in order to avoid confusion.

Claims 3 and 11 recite 'before a meal.' This phrase is not clearly delineated because the term 'before a meal' could mean an infinite amount of time in the past. If Applicants intend for this to mean directly prior to a meal, it is suggested that the claim be narrowed to include this limitation to provide clarity.

Claim 9 recites 'the body.' This term lacks antecedent basis in the claim. Further, the claim recites '...the method comprising the steps for:....' This phrase is confusing in that the meets and bounds of the word 'for' are not clearly delineated. It is suggested that the claim be reworded to read '..wherein the method comprises the following steps..' in order to avoid confusion.

Claim 12 recites '..from puree of French Polynesia.' The Examiner could not find a description or definition which explained 'puree of French Polynesia.' Is this the pure *Morinda citrifolia* fruit as a concentrated form, or is it a brand name of a concentrated fruit juice which may contain other ingredients besides *Morinda citrifolia* fruit? Lacking a clear description of this term, the ordinary artisan would be confused as to what the Applicants mean by 'puree of French Polynesia.'

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirazumi et al. (1999).

Claims 1 and 9 are respectively drawn to a method for reducing cellular damage and a method for scavenging lipid hydroperoxides and superoxide anion free radicals via administration of *Morinda citrifolia* juice. Claims 2-4 and 10-11 are drawn to wherein the method includes a specific recommended use, wherein the recommended use comprises consuming the dietary supplement before a meal and wherein the fruit of *Morinda citrifolia* is harvested, processed and packaged.

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Hirazumi et al. (1999) disclosed that *Morinda citrifolia* (noni) juice provided anti-tumor activity when administered to mice with active tumors (p.2). Hirazumi et al. disclosed that the effective dose was about 6-15mg of noni juice per mouse. As it is known in the art, one milliliter equals approximately one gram. Thus, the Examiner concludes that the mouse received approximately 6-15ml of the noni juice which was less than 'one fluid ounce' in a day. Because the term 'meal' is not clearly delineated (*supra*) it is deemed that the mice were administered the noni juice before a 'meal' since a meal would have eventually come (Hirazumi et al. indicated that the treatments prolonged the life span of the mice, indicating that they must have been fed after the initial treatment).

The fruit must have been harvested in order to have prepared the juice from them (p.1). Further, the compositions were injected, and thus were 'packaged' within an injection device such as a syringe.

Because Hirazumi et al. taught a method for decreasing tumors in mice, the method would have inherently scavenged lipid hydroperoxides and superoxide anions since the method steps in the treatment were the same.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirazumi et al. (1999). Claims 5-8 and 12 are drawn to wherein the fruit is harvested when it is at least one inch long and up to twelve inches in diameter, wherein the fruit is cleaned, harvested, separated from spoiled fruit and placed in plastic lined containers, wherein the juice is separated from the solids of the fruit such as seeds, peel or pulp, mixing the juice with a flavor or sweetener for example and heating the dietary supplement to a temperature of at least 181°F, wherein the supplement is packaged in a glass or plastic container, and wherein the supplement includes reconstituted *Morinda citrifolia* fruit juice from pure juice puree of French Polynesia.

Hirazumi et al. (1999) did not specifically teach wherein the fruit is harvested when it is at least one inch long and up to twelve inches in diameter, wherein the fruit is cleaned, harvested, separated from spoiled fruit and placed in plastic lined containers, wherein the juice is separated from the solids of the fruit such as seeds, peel or pulp, mixing the juice with a flavor or sweetener for example and heating the dietary supplement to a

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temperature of at least 181°F, wherein the supplement is packaged in a glass or plastic container, and wherein the supplement includes reconstituted *Morinda citrifolia* fruit juice from pure juice puree of French Polynesia.

Specific limitations regarding harvesting, cleaning, or wherein the juice was separated from the solids of the fruit or wherein the fruit is mixed with a sweetener does not materially change the method. The term 'juice,' as defined by Webster's Dictionary, means 'the liquid part of a plant, fruit, or vegetable.' Further, Hirazumi et al. explained that they allowed the juice to seep out of the fruit. Thus, it is deemed that the liquid of the fruit was separated from solids such as the seeds and the peel.

It was routine in the art of pharmacology to admix active ingredients with carriers, colorings and sweeteners for example. Carriers were an advantageous means of diluting active ingredients to necessary dosage ranges. Further, sweeteners and colorings would not have changed the medicinal qualities of the noni. One of ordinary skill in the art would have been motivated to have added carriers and sweeteners to noni juice in order to have formulated noni juice compositions containing varying percentages of active ingredients (i.e., 'regular' -vs- 'extra strength') as well as for mere ease of delivery.

It was also routine in the art to heat pharmaceutically active ingredients obtained from natural sources to temperatures to about 181° F in order to kill any potential bacteria/fungus which may have been present. One of ordinary skill in the art would have

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been motivated to have heat-killed the juice in order to eliminate any bacteria or fungus which may have had the potential to make a patient ill.

Although the reference does not teach wherein the noni fruit is harvested when it is at least one inch long and twelve inches in diameter, the Examiner deems that the fruit, containing intrinsic phytochemicals, would have contained these phytochemicals (active ingredients) at most of the growing stages of the fruit. The Examiner cannot find any evidence within the Instant specification which clearly indicates that the harvesting limitations found in the claims materially changes the characteristics of noni. Thus, it is deemed that the method for harvesting does not clearly change the method for reducing cellular damage, since the fruit, as instantly claimed in Claim 5 is substantially the same fruit as described by Hirazumi et al. especially lacking clear, credible evidence to the contrary.

Further harvesting limitations such as separating spoiled fruit, and placing the harvested fruit in a plastic container does not materially change the method for reducing cellular damage. Applicants are merely reciting pre-operative steps which do not limit the method for reducing cellular damage.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary

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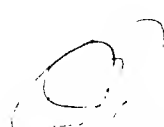
skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER R. TATE
PRIMARY EXAMINER